

REMARKS

The Office Action mailed July 13, 2007, has been received and reviewed. Claims 1, 7-21 and 25-56 are currently pending and under consideration in the application. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. No new matter has been added. Reconsideration is respectfully requested.

Interview Summary

Applicants would like to thank the Examiner for the courtesy extended Applicants' representatives during the interview of October 2, 2007. Pursuant to MPEP § 713.04, Applicants state the following:

During the interview, the Office communication mailed July 13, 2007 was discussed in general, claim amendments to overcome the indefiniteness rejection were discussed, and further the obviousness-type double patenting rejections were discussed. It appeared in the interview that the amendments would overcome the indefiniteness rejection and the Examiner indicated that further consideration will be given.

Applicants' representative believes that the Examiner Interview Summary, together with the instant Amendment adequately describes the substance of the interview. If, however, the Office would like further information, the Examiner is kindly requested to contact Applicants' undersigned representative, and further detail will be promptly provided.

35 U.S.C. § 112, second paragraph, Indefiniteness Rejections

Claims 7 and 25 were rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to point out and distinctly claim the subject matter which the applicants regard as the invention.

Applicants have amended claims 7 and 25 in the manner indicated by the Examiner to be remedial (Office Action, page 4), and in view of the amendment therefore respectfully request that the rejection be withdrawn.

Obviousness-Type Double Patenting

U.S. Patent Application No.10/499,298

Claims 1, 7-9, 11-13, 17, 21, 25, 26, 28, 32-34, 38, 42-44, 49-51, and 55 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 25, 26, 30, 31, 35, 36, 50-55, 59-63, and 65-68 of co-pending Application No. 10/499,298.

To expedite prosecution, a terminal disclaimer is enclosed herewith to overcome the provisional nonstatutory obvious type double patenting rejection.

U.S. Patent Application No.11/593,279

Claims 1, 7-9, 11-13, 17, 18, 32-34, 38, and 39 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 28-50, 89, and 90 of co-pending Application No. 11/593,279.

To expedite prosecution, a terminal disclaimer is enclosed herewith to overcome the provisional nonstatutory obvious type double patenting rejection.

U.S. Patent 7,262,028 (issued from U.S. Patent Application No.11/039,767)

Claims 21, 25, 26, 42-44, and 49-51 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent 7,262,028.

To expedite prosecution, a terminal disclaimer is enclosed herewith to overcome the provisional nonstatutory obvious type double patenting rejection.

U.S. Patent Application No.11/592,409

Claims 21, 25-29, 42-45, 48-52, 55, and 56 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-57 of co-pending Application No. 11/592,409.

To expedite prosecution, a terminal disclaimer is enclosed herewith to overcome the provisional nonstatutory obvious type double patenting rejection.

U.S. Patent Application No. 11/280,757

Claims 1, 7-9, 17, 18, 20, 21, 25, 26, 28, 29, 38, 39, 41, 55, and 56 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-23 of co-pending Application No. 11/280,757.

To expedite prosecution, a terminal disclaimer is enclosed herewith to overcome the provisional nonstatutory obvious type double patenting rejection.

U.S. Patent Application No. 11/110,517

Claims 1, 7-9, 15, 21, 25, 26, 36, 46, and 53 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-22, 29, and 30 of co-pending Application No. 11/110,517.

As none of the allegedly conflicting claims in question have in fact been patented, Applicants hold their response to the same in abeyance until such time as subject matter has been found patentable.

If the only remaining rejection in the present application is a provisional double patenting rejection, it is respectfully requested to withdraw this rejection (see, MPEP 804.I.B).

U.S. Patent Application No. 11/271,368

Claims 21, 25, 26, 29, 46, 47, 53, 54, and 56 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claim 1-36 of co-pending Application No. 11/271,368.

As none of the allegedly conflicting claims in question have in fact been patented, Applicants hold their response to the same in abeyance until such time as subject matter has been found patentable.

If the only remaining rejection in the present application is a provisional double patenting rejection, it is respectfully requested to withdraw this rejection (see, MPEP 804.I.B).

U.S. Patent Application No. 11/450,038

Claims 1, 7-9, 15, 16, 36, and 37 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 31-34, and 37 of co-pending Application No. 11/450,038.

As none of the allegedly conflicting claims in question have in fact been patented, Applicants hold their response to the same in abeyance until such time as subject matter has been found patentable.

If the only remaining rejection in the present application is a provisional double patenting rejection, it is respectfully requested to withdraw this rejection (see, MPEP 804.I.B).

U.S. Patent Application No. 11/256,352

Claims 21, 25, 26, 29, 46, 47, 53, 54, and 56 are provisionally rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-14 and 18 of co-pending Application No. 11/256,352.

As none of the allegedly conflicting claims in question have in fact been patented, Applicants hold their response to the same in abeyance until such time as subject matter has been found patentable.

If the only remaining rejection in the present application is a provisional double patenting rejection, it is respectfully requested to withdraw this rejection (see, MPEP 804.I.B).

U.S. Patent 7,192,759

Claims 21, 25, 26, 46, 47, 53, and 54 are rejected under the judicially created ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent 7,192,759. Applicants traverse the remaining rejections as set forth.

It is respectfully submitted that the invention in the instant claims is fundamentally different from the invention claimed in U.S. Patent 7,192,759. The instant application is directed to recombinant protein production by introduction of nucleic acid encoding the protein into the cells, such that the nucleic acid integrates into the genome, and therewith is stably inherited within the progeny of the cells, ensuring stable production of recombinant proteins from the cells. Indeed, all instant claims require that the **recombinant nucleotide sequence in**

expressable format forms part of the genome of the eukaryotic cell. In contrast to the present invention, the invention in US Patent 7,192,759 is based on the finding that viruses can infect the cells and replicate in the cells after infection of the cells with such viruses. In contrast to the claimed subject matter of the present invention, U.S. Patent 7,192,759 does not teach or suggest the integration of a nucleic acid encoding a protein of interest into the genome of the cell. In contrast to the instant claims, the influenza virus of the claims of U.S. Patent 7,192,759 does not integrate nucleic acid into the genome of the cells, but rather replicates in the cells such that the influenza virus may be harvested from the cells for use in vaccines.

Therefore, applicants submit that claims 21, 25, 26, 46, 47, 53, and 54 of the present application and claims 1-21 of U.S. Patent 7,192,759 are not obvious in view of one another, and thus are patentably distinct over each other.

Therefore, it is respectfully submitted that the obviousness-type double patenting rejections of claims 21, 25, 26, 46, 47, 53, and 54 over claims 1-21 of U.S. Patent 7,192,759 is inappropriate. Reconsideration and withdrawal of the rejection is respectfully requested in view of the foregoing.

Response to Arguments

The Office Action indicates that “[c]ommonly assigned Applications (10/499,298; 11/593,279; 11/039,767; 11/280,757, 11/110,517; 11/271,368; 11/450,038; 11/256,352; 10/644,256; 11/271,090; and 11/026,518) and commonly assigned Patent 7,192,759...would form the basis for a rejection under 35 U.S.C. § 103(a).” Office Action of July 13, 2007, page 19.

With respect to rejections under 35 U.S.C. § 103(a) that are based upon references which qualify as prior art under 35 U.S.C. § 102(e), 35 U.S.C. § 103(c) provides:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Statement to disqualify references under 35 U.S.C. § 103(c)

At the time the invention disclosed in the present application and in U.S. Patent Application Nos. 10/499,298; 11/593,279; 11/039, 767; 11/110,517; 11/217,368; 11/450,038; 11/256,352; 10/644,256; 11/271,090; and 11/026,518 and U.S. Patent 7,192,759 was made, it was owned by or subject to an obligation of assignment to Crucell Holland B.V. Crucell Holland B.V. is the same party to which each of U.S. Patent Application Nos. 10/499,298; 11/593,279; 11/039, 767; 11/110,517; 11/217,368; 11/450,038; 11/256,352; 10/644,256; 11/271,090; and 11/026,518 and U.S. Patent 7,192,759 had already been assigned.

Exhibit A is submitted herewith to provide objective evidence of the assignments.

Accordingly, the U.S. Patent Applications and the U.S. Patent cited in the Office Action may not be relied upon in a rejection of any of the claims of the present application under 35 U.S.C. § 103(a) (see, M.P.E.P. § 706.02(1)(2)).

Serial No. 10/790,562

The application should now be in condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact Applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Dan Morath', written in a cursive style.

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Date: October 15, 2007
TH/th



PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hateboer et al.

Serial No.: 10/790,562

Filed: March 1, 2004

For: RECOMBINANT PROTEIN
PRODUCTION IN A HUMAN CELL

Confirmation No.: 9903

Examiner: M. Joike

Group Art Unit: 1636

Attorney Docket No.: 2578-4038.3US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Oct. 15, 2007
Date

Betty Vowles
Signature

Betty Vowles
Name (Type/Print)

EXHIBIT A

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Assignee, CRUCCELL HOLLAND, B.V., a Netherlands Corporation, having a place of business at Archimedesweg 4, 2333 CN Leiden, Netherlands, is the assignee of the entire right, title and interest in the following:

1. U.S. Patent Application 2005/0048038, filed October 25, 2004 and assigned Application Serial No. 10/499,298, by virtue of the chain of title from the inventors to the assignee, as shown below:

Serial No. 10/790,562

a. From inventor David Halford Ashton Jones to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on October 25, 2004, at Reel/Frame 015915/0252.

b. From inventor Abraham Bout to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on October 25, 2004, at Reel/Frame 015915/0252.

2. U.S. Patent Application 2007/0077624, filed November 6, 2006 and assigned Application Serial No. 11/593,279, by virtue of the chain of title from the inventors to the assignee, as shown below:

a. From inventor Patrick H. C. Van Berkel to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 6, 2006, at Reel/Frame 018570/0161.

b. From inventor Ronald Hendrik Peter Brus to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 6, 2006, at Reel/Frame 018570/0161.

c. From inventor Ton Logtenberg to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 6, 2006, at Reel/Frame 018570/0161.

d. From inventor Abraham Bout to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 6, 2006, at Reel/Frame 018570/0161.

3. U.S. Patent Application 2005/0170398, filed January 18, 2005 and assigned Application Serial No. 11/039,767, by virtue of the chain of title from the inventors to the assignee, as shown below:

- a. From inventor Patrick H. C. Van Berkel to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on January 18, 2005, at Reel/Frame 016220/0866.
- b. From inventor Ronald Hendrik Peter Brus to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on January 18, 2005, at Reel/Frame 016220/0866.
- c. From inventor Ton Logtenberg to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on January 18, 2005, at Reel/Frame 016220/0866.
- d. From inventor Abraham Bout to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on January 18, 2005, at Reel/Frame 016220/0866.

4. U.S. Patent Application 2006/0099685, filed November 15, 2005 and assigned Application Serial No. 11/280,757, by virtue of the chain of title from the inventors to the assignee, as shown below:

- a. From inventor Christopher A. Yallop to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 15, 2005, at Reel/Frame 017249/0226.

Serial No. 10/790,562

b. From inventor Dirk Jan Elbertus Opstelten to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 15, 2005, at Reel/Frame 017249/0226.

c. From inventor Abraham Bout to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 15, 2005, at Reel/Frame 017249/0226.

5. U.S. Patent Application 2005/0186222, filed April 20, 2005 and assigned Application Serial No. 11/110,517, by virtue of the chain of title from the inventors to the assignee, as shown below:

a. From inventor Alphonsus G. C. M. Uytdehaag to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on April 20, 2005, at Reel/Frame 016499/0222.

b. From inventor Govert Johan Schouten to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on April 20, 2005, at Reel/Frame 016499/0222.

c. From inventor Jaap Goudmit to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on April 20, 2005, at Reel/Frame 016499/0222.

6. U.S. Patent Application 2006/0051747, filed November 11, 2005 and assigned Application Serial No. 11/271,368, by virtue of the chain of title from the inventors to the assignee, as shown below:

- a. From inventor Maria Grazia Pau to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on August 2, 2007 at Reel/Frame 019639/0873.
- b. From inventor Alphonsus G. C. M. Uytdehaag to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on August 2, 2007 at Reel/Frame 019639/0873.
- c. From inventor Govert Johan Schouten to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on August 2, 2007 at Reel/Frame 019639/0873.

7. U.S. Patent Application 2007/0072207, filed June 8, 2006 and assigned Application Serial No. 11/450,038, by virtue of the chain of title from the inventors to the assignee, as shown below:

- a. From inventor Maria Grazia Pau to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on June 8, 2006, at Reel/Frame 017990/0282.

Serial No. 10/790,562

b. From inventor Alphonsus G. C. M. UytdeHaag to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on June 6, 2006, at Reel/Frame 017990/0282.

8. U.S. Patent Application 2006/0063261, filed October 21, 2005 and assigned Application Serial No. 11/256,352, by virtue of the chain of title from the inventors to the assignee, as shown below:

a. From inventor Maria Grazia Pau to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 28, 2005, at Reel/Frame 017272/0711.

b. From inventor Alphonsus G. C. M. UytdeHaag to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 28, 2005, at Reel/Frame 017272/0711.

c. From inventor Govert Johan Schouten to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 28, 2005, at Reel/Frame 017272/0711.

9. U.S. Patent Application Application No. 2005/0106722, filed August 20, 2003 and assigned Application Serial No. 10/644,256, by virtue of the chain of title from the inventors to the assignee, as shown below:

Serial No. 10/790,562

a. From inventor David Halford Ashton Jones to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on January 18, 2005, at Reel/Frame 016156/0963.

b. From inventor Abraham Bout to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on January 18, 2005, at Reel/Frame 016156/0963.

10. U.S. Patent Application Application No. 2006/0063234, filed November 9, 2005 and assigned Application Serial No. 11/271,090, by virtue of the chain of title from the inventors to the assignee, as shown below:

a. From inventor David H. A. Jones to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on November 9, 2005, at Reel/Frame 017235/0184.

11. U.S. Patent Application Application No. 2005/0164386, filed December 30, 2004 and assigned Application Serial No. 11/026,518, by virtue of the chain of title from the inventors to the assignee, as shown below:

a. From inventor Alphonsus G. C. M. Uytdehaag to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on March 31, 2005, at Reel/Frame 016406/0958.

b. From inventor Dirk J. E. Opstelten to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on March 31, 2005, at Reel/Frame 016406/0958.

12. U.S. Patent 7,192,759, filed November 26, 1999 and assigned Application Serial No. 09/449,854, by virtue of the chain of title from the inventors to the assignee, as shown below:

a. From inventor Maria Grazia Pau to Assignee Introgene B.V. This document was recorded with the United States Patent and Trademark Office on May 1, 2000, at Reel/Frame 010790/0504.

b. From inventor Alphonsus G. C. M. UytdeHaag to Assignee Introgene B.V. This document was recorded with the United States Patent and Trademark Office on May 1, 2000, at Reel/Frame 010790/0504.

c. From Assignor Introgene B.V. to Assignee Crucell Holland B.V. This document was recorded with the United States Patent and Trademark Office on October 11, 2005, at Reel/Frame 017076/0359.